GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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Alice E. Till, Ph.D.
President

April 1, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling [Docket No. 98D-1266]

Dear Sir/Madam:

On behalf of the Generic Pharmaceutical Industry Association (GPIA), I would like to submit comments to you on "Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling", 64 FR 18, 4434, January 28, 1999.

GPIA is comprised of manufacturers and distributors of generic medicines, as well as suppliers of services and goods to these firms. This guidance will positively impact many of our members, as well as their customers – physicians, pharmacists, and patients.

GPIA applauds FDA for drafting the subject guidance and fully endorses the concept of permitting the voluntary placement of the therapeutic equivalence code on prescription drug labels and labeling for all drugs.

We agree that the use of therapeutic equivalence codes will contribute to the accurate and safe selection of generic products by pharmacists. Further, where the labeling is provided intact to the consumer, it should provide additional assurance to the patient, or the patient caregiver, that the product dispensed is indeed equivalent to the reference product. To that end, we would like to suggest that the therapeutic equivalence rating be allowed to be prominently displayed in the package insert and in any patient information provided with the dispensed product, as well as on the immediate container and carton labeling, if desired by the manufacturer.

In those few instances, such as small volume parenterals, where there maybe concerns about the feasibility of safely including the equivalence rating on the label, an equally effective alternative should be identified on a case-by-case basis. Also, in those few cases where the agency requests, for safety reasons, that the equivalence rating be included on the prescription drug label, we would expect that it would enter into discussion with the manufacturer, relabeler, or distributor to determine the most appropriate means of compliance with this request.

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Again, GPIA endorses this step by FDA which will help promote the purpose of the ***Orange Book,*** assist the health professional in generic product selection, and serve state health agencies in the administration of their drug product selection laws.

Sincerely,

Alice E. Till, Ph.D.
President

cc M. Samson, Chair GPIA
J. Phillips, CDER, FDA

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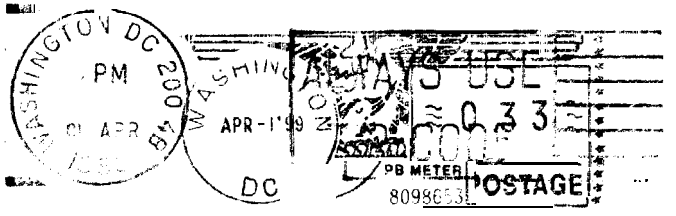

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